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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/549,978

11/15/2006

Martin Pruschy

4-32911A

3436

1095

7590

08/12/2011

NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 101/2
EAST HANOVER, NJ 07936-1080

EXAMINER

GEMBEH, SHIRLEY V

ART UNIT

PAPER NUMBER

1628

MAIL DATE

DELIVERY MODE

08/12/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/549,978	PRUSCHY, MARTIN	
	Examiner	Art Unit	
	SHIRLEY V. GEMBEH	1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 June 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,5 and 11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,5 and 11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/29/11</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. The response filed 6/29/11 has been entered.
2. Applicant's arguments filed 6/29/11 have been fully considered but they are not deemed to be persuasive.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Claims 1, 4-5 and 11 are pending in this office action.
5. The information disclosure statement (IDS) submitted on 6/29/11 is acknowledged and has been reviewed.

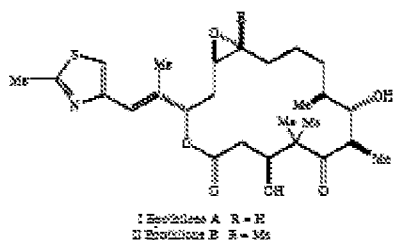
Maintained Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 4-5 and 11 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Danishefsky et al. (US Patent 6,242,469) in view of Bollag Exp. Opn. Invest. Drugs (1997) 6 (7):867-873 for the reasons made of record in Paper No. 20100404 and as follows.

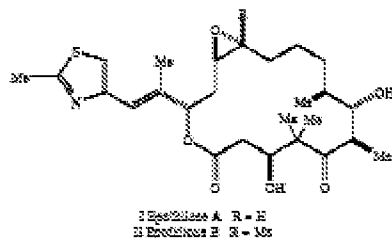
Danishefsky et al. teach using pharmaceutical compositions of epothilones A and



B (i.e., wherein A in Applicant's chemical formula is O, R is methyl and Z is O would represent structure II of Danishefsky) for the treatment of solid tumor in a subject, wherein the solid tumor is breast cancer (as required by instant claims 1-3, 5 and 11; see abstract and col. 28 line 49-56). Reasonably treatment of breast cancer in a subject meets the limitation of treating a warm-blooded animal (as required by instant claim 4).

However Danishefsky et al. fail to teach the combination of epothilone b in combination with ionizing radiation.

Bollag teaches numerous solid tumors may be treated with the compounds of



epothilones (i.e., , wherein A in Applicant's chemical formula is O, R is methyl and Z is O would represent structure II of Bollag) and further

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teaches that because of the similarity of function with a class of compounds (taxanes), epothilones possess similar or greater potencies than taxanes and should be further studied in combination with ionizing radiation, thus suggesting that these compounds can be combined with ionizing radiation.

It would have been obvious to one of ordinary skill in the art to expand the method of Danishefsky et al. to include the methods of Bollag because both Bollag teach or suggest the inclusion of ionizing radiation in the methods for treating solid tumors such as breast cancer.

The instant situation is amenable to the type of analysis set forth in In re Kerkhoven, 205 USPQ 1069 (CCPA 1980) wherein the court held that it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose in order form a third composition that is to be used for the very same purpose since the idea of combining them flows logically from their having been individually taught in the prior art. Applying the same logic to the instant method of treatment, given the teaching of the prior art methods of using Danishefsky et al. and Bollag individually for treating solid tumors, it would have been obvious to use both compounds for the treatment of solid tumors because the idea of doing so would have logically followed from their having been individually taught in the prior art to be useful as therapeutic agents.

Applicant argues that “[t]he Examiner notes that Danishefsky et al fail to teach the combination of epothilone B in combination with ionizing radiation, Bolag et al merely suggests that “the value of epothilones and discodermolide should be explored

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in cells in combination with agents such as radiation which induce the G1 block-mediated apoptosis." Thus the combined disclosure of the reference merely suggests to conduct experiments, However, it does not provide a basis for the skilled artisan to reasonably expect that epothilone B and radiation therapies could successfully be combined for the treatment of solid tumors, Therefore, the present :claims: are not prima facie obvious over the combined disclosure of the references.

Additionally Applicant argues that the journal article report synergy when epothilone B is combined with radiation.

In response contrary to Applicant's assertion Applicant's arguments are found not persuasive for the following reasons:

Applicant is correct in stating that Danishevsky fails to teach the combination of epothilone with radiation, it is for this very reason that Bollag was added. Applicant should note that this rejection is under 35 USC 103 and the combined cited prior art should be taken into consideration. The fact that Bollag teaches that epothilone can be used with radiation is enough to motivate one of ordinary skill in the art to at least try. That being said, it must be remembered that "[w]hen a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious". KSR v. Teleflex, 127 S.Ct. 1727, 1740 (2007)(quoting Sakraida v. A.G. Pro, 425 U.S. 273, 282 (1976)). "[W]hen the question is whether a patent claiming the combination of elements of prior art is obvious", the relevant question is "whether the improvement is more than the predictable use of prior art

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elements according to their established functions." (Id.). Addressing the issue of obviousness, the Supreme Court noted that the analysis under 35 USC 103 "need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." KSR v. Teleflex, 127 S.Ct. 1727, 1741 (2007). The Court emphasized that "[a] person of ordinary skill is... a person of ordinary creativity, not an automaton." Id. at 1742.

As already made of record and repeated here the provision of journal articles with regards to the claims are not persuasive because according to "B. Hofstetter et al, Clinical Cancer Research, Vol. 11, 1588-1596 (2005)" and "Bley et al, Clinical cancer Research, Vol. 15(4), 1335-1342 (2009)" the additive result achieved were only observed with specific dosage concentrations, and alternatively the claims are very broad with no recited dosage amounts (see pages 1590-91 Fig's 1 and 2 of the result section of the Hofstetter and page 1338 of Bley).

Applicant should note that in Ex parte Gelles 22 USPQ 2d 1318 (at 1319): held that "[t]he evidence relied upon also should be reasonably commensurate in scope with the subject matter claimed and illustrate the claimed subject matter "as a class" relative to the prior art subject matter." Also in order to show unexpected result's three major points that should be considered: the unexpected result must truly be unexpected, it must be commensurate in scope (show a trend representing the scope), and lastly a direct comparison with the closest prior art of record should be provided.

After careful consideration Applicant's argument is found not persuasive for the reasons given.

7. No claim is allowed.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHIRLEY V. GEMBEH whose telephone number is (571)272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, BRANDON FETTEROLF can be reached on 571-272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SHIRLEY V GEMBEH/
Examiner, Art Unit 1628
8/9/11

/Brandon J Fetterolf/
Supervisory Patent Examiner, Art Unit 1628